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10/618,413	07/11/2003	Fred Wehling	208-017US1	6803

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,413	WEHLING ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Informality

Claim 10, the word "a" should be inserted before "vitamin".

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7, 9, 12-15, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The term "substantially uniform" in claims 4, 18 and 19 is a relative term which renders the claims indefinite. The term "substantially uniform" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "uniform" is itself a term of degree insofar as it reflects an ideal; there is in reality no perfectly "uniform" dispersion. Accordingly, the term "substantially" is appended to an otherwise definite phrase, rendering its use as a modifier unclear and superfluous.

Since the term "substantially" is not necessary to an understanding of the claimed subject matter, the examine recommends deleting it in order to obviate this ground of rejection.

2) The metes and bounds of the recited percentage values in claims 7 and 12-15 are unclear because the basis for their determination is not set forth, *i.e.* percent by weight based on the total weight of the composition, percent by weight based on the combined weight of glucosamine and chondroitin, percent by weight based on the weight of the effervescent agent, *etc.* See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite without specifying the particular method used).

This ground of rejection can be overcome by amending each of claims 7 and 12-15 to end with the phrase ", wherein said percentage(s) is/are based on the total weight of the effervescent composition".

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-5, 10-15 and 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips (US Pub. 2003/0180389).

The patent discloses effervescent powders and tablets (paragraph [0025]) comprising 7.07% glucosamine, 5.66 % chondroitin, and an effervescent agent. See paragraph [0037]. Vitamins such as ascorbic acid and riboflavin are included as well (paragraphs [0031] and [0035]). Insofar as can be determined, these form "clear" solutions upon dissolving in water. Regarding the specific limitations of instant claim 3, 22 and 23, these appear to recite nothing more than the inherent characteristics of typical effervescent tablets, and accordingly do not appear to distinguish the instantly claimed subject matter from that of the prior art in any meaningful way. (Certainly it is reasonable to expect a small mass (7g) of prior art composition to dissolve completely in a large volume (200 to 400ml) of water, for instance).

2) Claims 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wehling (USP 6,811,793).

The patent discloses effervescent powders and tablets containing glucosamine (column 5, line 29) which form clear solutions upon dissolving in water. (Note that the reference explicitly describes hardness values of at least 6 kp (column 1, lines 48-60), providing objective evidence tending to support the assertion made by the examiner in subsection "1)' supra.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-5, 8-15 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wehling et al (USP 6,811,793).

The patent discloses effervescent compositions which form clear solutions upon dissolving in water. Various limitations of the dependent claims are met as follows:

a) calcium is included as a mineral supplement (column 5, line 22), meeting the requirements of instant claims 5 and 6;

b) the base of the effervescent couple may be magnesium carbonate (column 2, line 17), meeting the requirements of instant claims 8 and 9;

c) vitamins are included, *e.g.*, riboflavin (column 4, last paragraph), meeting the limitations of instant claims 10 and 11; and

d) the tablets have hardness values of at least 6Kp (column 1, lines 47-60), meeting the limitations of instant claims 22 and 23.

The prior art thus differs substantively from the instant claims only insofar as it does not specifically disclose using a mixture of chondroitin and glucosamine. It does clearly suggest same, however, at column 5, lines 30 and 31, and it would have been obvious to have used such mixtures in accordance with that teaching. Regarding the specific weight percentage limitations of instant claims 12-15, the examiner takes the position that it would have been obvious for one skilled in the art to have determined useable and/or optimal percentages of each component using no more than routine experimentation, consistent with the reasoning set forth in well-established precedent, *e.g.*, In re Aller, 105 USPQ 233, 235 (CCPA 1955), In re Boesch, 205 USPQ 215 (CCPA 1980), and In re Peterson, 315 F.3d 1325 (C.A. Fed 2003).

2) Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pub. 2003/0180389) in view of Fox (US Pub. 2001/0018082).

The primary reference is discussed in subsection "1)' of the "Anticipation" section supra, and differs from the instant claims in its silence regarding calcium lactate. It does, however, suggest the incorporation of additional calcium (beyond that provided in the form of calcium carbonate, when same is used as the primary effervescent base) as a nutritional supplement at paragraph [0033].

The secondary reference teaches that calcium lactate is a preferred secondary calcium source for calcium supplementation of effervescent compositions (see paragraph [0026], for instance) which are completely soluble in water, providing clear solutions free of cloudiness or residue (paragraph [0013]. It differs from the instant claims in its silence regarding glucosamine and chondroitin.

It would have been obvious to have incorporated calcium lactate as a secondary calcium source into the effervescent compositions of the primary reference, motivated by the desire to provide calcium supplementation while maintaining solubility and clarity as taught by the secondary reference.

3) Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wehling et al (USP 6,811,793) in view of Fox (US Pub. 2001/0018082).

The primary reference is discussed in subsection "2)" of the "Anticipation" section supra, and differs from the instant claims in its silence regarding calcium lactate. It does, however, suggest the incorporation of additional calcium (beyond that provided

in the form of calcium carbonate, when same is used as the primary effervescent base) as a nutritional supplement at column 5, lines 23-25.

The secondary reference teaches that calcium lactate is a preferred secondary calcium source for calcium supplementation of effervescent compositions (see paragraph [0026], for instance) which are completely soluble in water, providing clear solutions free of cloudiness or residue (paragraph [0013]. It differs from the instant claims in its silence regarding glucosamine and chondroitin.

It would have been obvious to have incorporated calcium lactate as a secondary calcium source into the effervescent compositions of the primary reference, motivated by the desire to provide calcium supplementation while maintaining solubility and clarity as taught by the secondary reference.

4) Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pub. 2003/0180389) in view of Little (USP 1,616,587).

The primary reference is discussed in subsection "1)" of the "Anticipation" section supra, and differs from the instant claims in its silence regarding magnesium.

The secondary reference teaches that it is known to incorporate magnesium sulfate into effervescent compositions in order to normalize the balance with magnesium naturally present in the user's body. See column 1, lines 11-24. It differs from the instant claims in its silence regarding glucosamine and chondrotin.

It would have been obvious to have incorporate magnesium sulfate into the effervescent compositions of the primary reference, motivated by the desire to balance physiological magnesium levels in the user as taught by the secondary reference.

5) Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pub. 2003/0180389) in view of Fox (US Pub. 2001/0018082), the combination being taken further in view of Little (USP 1,616,587).

The primary and secondary references, and the motivation for combining their teachings, are discussed in subsection "2)" supra. Their combined disclosures differ from those of the instant claims in their silence regarding magnesium sulfate.

The tertiary reference teaches that it is known to incorporate magnesium sulfate into effervescent compositions in order to normalize the balance with magnesium naturally present in the user's body. See column 1, lines 11-24. It differs from the instant claims in its silence regarding glucosamine and chondrotin.

It would have been obvious to have incorporate magnesium sulfate into the effervescent compositions suggested by the combined teachings of the primary and secondary references, motivated by the desire to balance physiological magnesium levels in the user as taught by the tertiary reference.

6) Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wehling (USP 6,811,793) in view of Fox (US Pub 2001/00818082), the combination being taken further in view of Little (USP 1,616,587).

The primary and secondary references, and the motivation for combining their teachings, are discussed in subsection "3)" supra. Their combined disclosures differ from those of the instant claims in their silence regarding magnesium sulfate.

The tertiary reference teaches that it is known to incorporate magnesium sulfate into effervescent compositions in order to normalize the balance with magnesium naturally present in the user's body. See column 1, lines 11-24. It differs from the instant claims in its silence regarding glucosamine and chondrotin.

It would have been obvious to have incorporate magnesium sulfate into the effervescent compositions suggested by the combined teachings of the primary and secondary references, motivated by the desire to balance physiological magnesium levels in the user as taught by the tertiary reference.

Technological Background Material

The following art is cited to demonstrate the state of the art. Although pertinent, it has not been applied in a substantive rejection *per se*.

Iorio et al. teach that it is known in the effervescent tablet art that calcium lactate, when used with the effervescent couple calcium carbonate/fumaric acid, provides improved dissolution and clarity. See especially column 3, lines 35-45.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday-Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614